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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,291	01/25/2006	Isabel Cristina Gonzalez Valcarcel	X15998	5059

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EXAMINER	
MABRY, JOHN	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
03/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,291	GONZALEZ VALCARCEL ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,10-14,16,18,19,21,23,26,27,29-31 and 43* is/are pending in the application.

4a) Of the above claim(s) *5-7,14,18,21,23,26,27,30 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-13,16,19,29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant(s) is required to amend claims with respect to restricted group.

Examiner's Response

Applicant's response on January 18, 2008 filed in response to the Election/Restriction dated December 18, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group III with traverse. The Applicant requested that the method of treatment claim (claim 43) be rejoined when products are allowable. This request is duly noted. However, due to Examiner's Election/Restriction, the method of treatment claim 43 was properly restricted and was not considered in this Office Action.

Applicant requested that Groups (IV and V) are directed to the same group and (XI and XII) are directed to group. The Examiner is persuaded and these groups will be rejoined in a future divisional application.

It was Examiner's understanding that in elected group III, Z=phenyl/naphthyl-T-pyridinyl meant that "a phenyl or napthyl group is bonded through T to a pyridinyl group" in that order, where bonding to Formula I is through the phenyl or naphthyl. Examiner was uncertain of the order of bonding to Formula I, either through the pyridinyl group or the phenyl/naphthyl group. Examiner examined both bonding patterns and is reflected in the current office action.

Thus, the restriction requirement is deemed proper and **FINAL**.

In view of this response, the status of the rejections/objections of record is as follows:

Specification Objections

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Examiner suggests a title that directed towards elected group.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "substituted carbon bearing A2 and R3" in respective claims are relative terms which renders the claim indefinite. The phrase "substituted carbon bearing A2 and R3" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Additionally, the term "substituted carbon bearing A2 and R3" is a relative term which renders the claim indefinite. The phrase "substituted carbon bearing A2 and R3" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "substituted carbon bearing A2 and R3" has no clear limitations. What does the Applicant intend by this term? Additionally, please indicate where in the Specification is such support.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R3 being hydrogen and alkyl and R7 being hydrogen, halo, haloalkyl, alkyl, alkoxy, does not reasonably provide enablement for R3, R7, R8 and R9 being the following as described below.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Specification does not provide any support for said variables at R3, R7, R8 and R9 positions. The Specification describe starting materials and methods for synthesis of compounds wherein R3 being hydrogen and alkyl and R7 being hydrogen, halo, haloalkyl, alkyl, alkoxy, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R3, R7, R8 and R9 being the following as described below.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted phenoxy compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted phenoxy compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor.

See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. The Specification describes starting materials and methods for synthesis of compounds R3 being hydrogen and alkyl and R7 being hydrogen, halo, haloalkyl, alkyl, alkoxy, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R3, R7, R8 and R9 as described below. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The specification does not provide any support for the synthesis of compounds, wherein R3, R7, R8 and R9 being and that are substituted by the following:

R^3 is:

nitro,
cyano,
hydroxyl,
halo,
haloalkyl,
haloalkyloxy,
aryloxy,

C_1-C_6 alkoxy, or
C_3-C_8 cycloalkyl;

R^7 is:

oxo,
nitro,
cyano,
hydroxyl,

haloalkyloxy,
aryloxy,
arylalkyl,
aminoalkyl,

$(CH_2)_0C_3$-C_8 cycloalkyl,
$C(O)R^9$,
$C(O)OR^9$,
$C(=NOR^8)R^9$,
$CR^8(OH)R^9$,
$C[=C(R^g)_2]R^9$,
OR^9,
SR^8 or
$S(O)_0R^9$;

R^8 is: hydrogen or C_1-C_6 alkyl; and

R^9 is: hydrogen,
C_1-C_6 alkyl,
C_3-C_8 cycloalkyl,
aryl,
heteroaryl or
heterocyclyl,
wherein alkyl, cycloalkyl, aryl, heteroaryl or heterocyclyl being optionally substituted with one or more substituents selected from the group consisting of:

hydrogen, nitro, cyano, hydroxyl, halo, haloalkyl, haloalkyloxy, aryloxy, oxo, C_1-C_6 alkyl, C_1-C_6 alkoxy and C_3-C_8 cycloalkyl.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here…As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted phenoxy compounds wherein R3 being hydrogen and alkyl and R7 being hydrogen, halo, haloalkyl, alkyl, alkoxy, which are well documented in the art. So far as the examiner is aware, no substituted phenoxy compounds of general formula I as described in (4) any kind have been made or used.

It is not trivial to experimentally interchange any and all of the many substituents that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially

and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Wienheim.

(6) Working Examples: Applicant shows examples but no working examples were shown wherein R3, R7, R8 and R9 of the aforementioned substituents have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide,

and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salts, does not reasonably provide enablement for hydrates and solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to hydrates and solvates. But the numerous examples presented all failed to produce a hydrate or solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

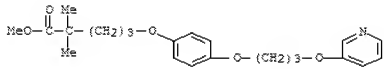
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kojima et al (US 4,795,753 A).

The instant application discloses compounds of Formula I wherein Q=CO2CH3, R4 and R5=H, A1, A2, A3=O, E1-E5=phenyl, R1 and R2=H, Y=-(CH2)3 and Z=pyridyl substituted with phenyl.

Scope & Content of Prior Art MPEP 2141.01

The instant application discloses compounds and pharmaceutical compositions of Formula I wherein Q=CO2CH3, R4 and R5=CH3, A1, A2, A3=O, E1-E5=phenyl, R1 and R2=H, Y=-(CH2)3 and Z=pyridyl (see Example 43, column 44).



Differences between Prior Art & the Claims MPEP 2141.02

The instant application differs from Kojima at positions:

(a) R4 and R5, Applicant's H versus Kojima's –CH3. A hydrogen (H) and methyl (-CH3) are deemed obvious variants (*In re Wood*, 199 USPQ 137) and

(b) Z, Applicant's pyridyl substituted with phenyl versus Kojima's pyridyl. However, Kojima teaches that compounds of Formula I can be substituted with phenyl (see lines 31-33, column 4).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

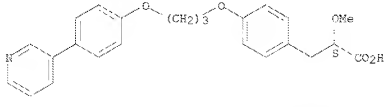
An artist of ordinary skill in the art would be motivated to take the teaching of Kojima et al and substitute methyl groups for hydrogen at the R4/R5 positions and substituted a phenyl group on the pyridyl group at position Z. Thus, said claims are deemed obvious by Kojima.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morishita et al (J. Med. Chem. 1988, 31, 1205-1209) in view of Brooks et al (WO 2002/100813 A2 – US equivalent 7,192,982 B2).

The instant application claims compounds and pharmaceutical compositions of formula I wherein Q=CO2H, R4 and R5=CH3, A1=O, E1-E5=phenyl, A2 and A3=CH2, R1 and R2=H, Y=a bond and Z=phenyl substituted with pyridyl.

Scope & Content of Prior Art MPEP 2141.01

Morishita discloses compounds of Formula I wherein Q=CO2H, R4 and R5=CH3, A1=O, E1-E5=phenyl, A2 and A3=CH2, R1 and R2=H, Y=a bond and Z=phenyl (see compound No. 5, Table I). Brooks discloses compounds and compositions of Formula I where in the phenyl group is substituted with a pyridyl group (see Example 271, column 293).



Differences between Prior Art & the Claims MPEP 2141.02

The instant application differs from Morshita at the the substitution on the phenyl ring. The instant application discloses compounds where Z= phenyl-T-pyridyl wherein T is a bond. Morishita disclose compounds where Z=phenyl-T-alkyl wherein T is a bond.

Broooks discloses compounds as claimed in Formula I where the phenyl group is substituted with a pyridyl group.

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

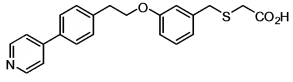
An artist of ordinary skill in the art would be motivated to combine the teachings of Morishita and Brooks to make compounds of as claimed in Formula I. It would be obvious to one of ordinary skill in the art to take the compounds of Morishita et al and substitute methyl for a pyridyl group at position Z as disclosed by Brooks in order to make compounds of formula. Thus, said claims are deemed obvious by Kojima.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima et al (US 7,211,591 B2).

The instant application claims compounds and pharmaceutical compositions of formula I wherein Q=CO2H, R4 and R5=H, A1=S, E1-E5=phenyl, A2=O and A3=CH2, R1 and R2=H, Y=a bond and Z=phenyl substituted with pyridyl.

Scope & Content of Prior Art MPEP 2141.01

Tajima discloses compounds and pharmaceutical compositions of formula I wherein Q=CO2H, R4 and R5=H, A1=CH2S, E1-E5=phenyl, A2=O and A3=CH2, Y=a bond and Z=phenyl substituted with pyridyl (see compound 25, column 69).



Differences between Prior Art & the Claims MPEP 2141.02

The instant application differs from Tajima at:

(a) the length of the alkylene group between the phenyl (E1-E5) and the Z group. Applicant's -(CH2)4- versus Tajima's -(CH2)2-. However, Tajima teaches and demonstrates that said alkylene unit can be C1-4alkylene (see column 7, lines 43).

and (b) the length of the alkylene group between the Q and the phenyl (E1-E5) group. Applicant's S versus Tajima's CH2S, which are considered homologs. Additionally, Tajima teaches that said subunit can be a bond and C1-C4 alkylene which is encompassed by the Applicant's claimed genus of Formula I (see column 8, lines 35-45).

The MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

An artist of ordinary skill in the art would be motivated to combine the teachings of Tajima to make compounds of as claimed in Formula I. It would be obvious to one of ordinary skill in the art to take the compounds of Tajima et al and extend the alkylene group between the phenyl (E1-E5) and the Z group to make compounds of formula I. One would be further motivated to shorten or extend the subunit between the Q and the

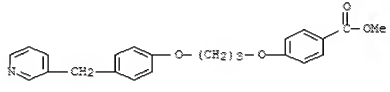
phenyl (E1-E5) group as disclosed by Tajima. Thus, said claims are deemed obvious by Tajima.

Claims 1-3, 10-13, 16, 19, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagi et al (JP 11302172 A) in view of Tajima et al (US 7,211,591 B2).

The instant application claims compounds and pharmaceutical compositions of formula I wherein Q=CO2CH3, R4 and R5=H, A1=CH2, E1-E5=phenyl, A2=O and A3=O, R1 and R2=H, Y=CH2 and Z=phenyl-CH2-pyridyl.

Scope & Content of Prior Art MPEP 2141.01

Takagi discloses compounds and pharmaceutical compositions of formula I wherein Q=CO2CH3, A1=a bond, E1-E5=phenyl, A2=O and A3=O, R1 and R2=H, Y=CH2 and Z=phenyl-CH2-pyridyl (see compound 47, page 10).



Differences between Prior Art & the Claims MPEP 2141.02

The instant application differs from Tajima at the length of the alkylene group between the Q and the phenyl (E1-E5) group. Applicant's –(CH2)2CO2CH3 versus Takagi's CO2CH3, which are considered homologs. Additionally, Tajima teaches that

said subunit can be a bond and C1-C4 alkylene which is encompassed by the Applicant's claimed genus of Formula I (see column 8, lines 35-45).

The MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH_2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

An artist of ordinary skill in the art would be motivated to combine the teachings of Takagi and Tajima to make compounds of as claimed in Formula I. It would be obvious to one of ordinary skill in the art to take the compounds of Takagi et al and shorten or extend (extending in this case) the subunit between the Q and the phenyl (E1-E5) group as disclosed by Tajima. Thus, said claims are deemed obvious.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625